



2016 Top Markets Report **Medical Devices** Country Case Study

Saudi Arabia

The Saudi health care sector is still the largest in the Near East North Africa region; the latest available figures indicate that the Saudi market for medical devices stood at \$1.72 billion in 2013 and was expected to reach \$1.88 billion in 2014 at more than 9 percent average annual growth. Imports account for more than 92 percent of the market at \$1.59 billion, and U.S. companies command the list of suppliers with a 21 percent share of total imports.

Overall Rank

23

Healthcare and education remain a top priority for the Saudi government, representing about 44 percent of government spending. Budgeted expenditures for the healthcare and social affairs sectors in 2015 were set at \$42.67 billion, a huge 48 percent growth from 2014 figures. Health care expenditures and delivery are dominated by the public sector, with government spending representing almost 79 percent of total spending on this sector, estimated at \$20 billion annually.

Local manufacturing is still limited to consumables, including bandages, gloves, syringes and some furniture, including non-electrical beds. Hospitals in Saudi Arabia are among the best equipped in this region, and the Ministry of Health sets aside an annual line item figure for "Replacement of Medical Equipment."

Market Entry

Although 100 percent foreign ownership of businesses in this sector is allowed, it is advisable that U.S. companies designate a local agent/representative to conduct business in Saudi Arabia. It is also advised that companies work with local legal counsel when drawing up a contractual agreement. Shari'a courts are the courts of general jurisdiction in the Saudi judicial system, and these

Country Highlights

Capital: Riyadh

Population: 29.9 million (est. 2014)

GDP (USD): 777.9 billion (2014)

Currency: Saudi riyal (SAR)

Language: Arabic (official)

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courts review all foreign court decisions to ensure consistency with Shari'a law.

Medical equipment is charged a 5 percent customs duty; in some instances, however, imported equipment is exempted, notably if the shipment is bound for a government entity and/or a government project.

Current Market Trends

Based on data from industry and the World Health Organization (WHO), Saudi Arabia, like other countries in the Arabian Gulf, continues to exhibit lifestyle change trends within its morbidity statistics. Non-communicable diseases, such as diabetes,

cardiovascular diseases and cancer, have become the main causes of death and are estimated to account for 78 percent of total deaths. Additionally, the Kingdom has one of the world's highest rates of traffic accidents, which, in 2012, resulted in 5,200 deaths.

In turn, those figures have been the key drivers for various equipment and services, namely:

- emergency and trauma equipment,
- rehabilitation equipment,
- diagnostic equipment,
- electro-medical equipment,
- hospital beds,
- orthopedic appliances and prosthesis,
- dental equipment,
- laboratory equipment,
- hospital operation and management,
- e-Health, and
- generic pharmaceuticals.

Moreover, the Kingdom was recently hit by the Middle East Respiratory Syndrome (MERS) virus, resulting in 282 deaths. Lifestyle changes have created additional pressure on available resources and demand for the health care system, which, in general, suffers shortages in the number of physicians, nursing and technical staff.

WHO data revealed that 20 percent of nationals over the age of 20 suffered from type-2 diabetes, 35 percent of Saudi adults are obese and more than 6.5 percent of the population has high blood pressure.

As the public sector dominates the supply of health care services by accounting for the majority of health care expenditures, it represents approximately 79 percent of bed capacity. Industry sources expect the government sector to outpace the private sector in the level of investments and beds capacity. The latest figures suggest that the MoH bed capacity will almost double to 73,768 beds; the private sector will add 13,875 beds, raising its capacity to 26,000; and other government organizations will total 20,000 beds by 2020.

The Saudi government's 10th five year development plan (2015–19) stipulates:

- Improving emergency medical services
- Improving SFDA control and supervisory services
- Enhancing the application of cooperative health insurance

- Provide training and developing the skills of workforce
- Improving the performance efficiency of management and operation systems
- Improving healthcare services for the special-needs groups
- Reviewing the regulations related with medical malfunctions and violations
- Improving healthcare safety
- Encouraging health establishments to obtain international accreditation.
- Establishing more primary health care centers and specialized curative services
- Improving the quality of health services provided to children, the aged and the disabled and expanding home health care for the aged and disabled persons
- Increasing the role of the private sector in provision of health services and expanding the scope of medicines and medical appliances manufacturing
- Enhancing the e-health system and the supporting information systems and expanding the scope of their use
- Developing the preventive and curative health services provided to pilgrims and Omra performers and ensuring Haj seasons free of diseases and epidemics

Main Competitors

The Saudi market is extremely dependent on imports for medical devices. U.S. suppliers enjoy some advantages, including competitive prices, language and exchange rate. European suppliers are aggressively gaining market share with their close proximity to the market and perceived better customer support.

Current Demand

Total health care expenditures in 2015 are expected to remain at 2014 levels (at nearly \$20 billion), due in part to lack of public funding for previous and ongoing projects, as well as the changes at the Ministry of Health administration (including a new minister). The demand for health care services has continuously outpaced supply, and both the public and private sectors are struggling to accommodate growing demand. A growing population, compulsory health insurance coverage and the prevalence of diseases are serving to boost the demand for

services and hospital bed occupancy. Today, the overwhelming majority of Saudi Arabia's 8.5 million health insurance holders are expatriates. The insurance reform could swell the pool with more than 1 million Saudi civil servants plus about 5 million dependents.

New projects in the 2015 MoH budget included the construction of three hospitals, three blood bank centers, 11 primary health care centers and 10 comprehensive care clinics. Hospital beds currently exceed 64,000 for all hospitals in Saudi Arabia, and this figure is expected to grow to 119,000 beds by 2020. Moreover, a private group of investors is developing Riyadh's Medical Village over a 250,000 sq. m. area, which will consist of eight 130-bed hospitals, 60 outpatient clinics and other amenities and services.

Additionally, the Executive Board of the Health Ministers' Council for the GCC states (HO in Riyadh) release an annual tender valued for a couple of billions of dollars for:

- Hospital sundries
- Renal Dialysis supplies
- Oral and dental care
- Laboratory sundries
- Orthopedic and spinal surgery
- Rehabilitation
- Cardiovascular
- Linens and medical uniforms
- Ophthalmology sundries
- ENT sundries
- Medicines
- Vaccines
- Chemicals
- Insecticides
- Radio-pharmaceuticals
- Renal dialysis solutions

Major players in the Saudi health care sector include (by expenditures):

- Ministry of Health
- Saudi Arabian National Guard
- Ministry of Defense and Aviation
- Ministry of Higher Education
- General Organization for Social Insurance
- Ministry of Interior
- Royal Clinics
- Johns Hopkins Aramco Healthcare

- Private Sector
- GCC State Health Ministers Council Executive Board

Registration Process

The Saudi Food and Drug Authority (SFDA) monitors and controls the import and distribution of medical devices, pharmaceuticals and food products. For medical devices, the SFDA will usually accept, register and authorize the marketing and sale of any device that complies with applicable provisions of the SFDA's Interim Regulations and relevant regulatory requirements applicable in one or more of the countries of the Global Harmonization Task Force (GHTF), which includes Australia, Canada, Japan, U.S. and EU/EFTA. More information on the registration process can be found at sfda.gov.sa/en.

Barriers

Commercial Dispute Settlement

There is not yet a transparent, comprehensive legal framework in place for resolving commercial disputes. Saudi commercial law is still developing, but in 1994, the Saudis took the positive step of joining the New York Convention of 1958 on the Recognition and Enforcement of Foreign Arbitral Awards. Saudi Arabia is also a member of the International Center for the Settlement of Investment Disputes (also known as the Washington Convention). Dispute settlement in Saudi Arabia, however, continues to be time-consuming and uncertain. Even after a decision is reached in a dispute, effective enforcement of the judgment can still take years. Generally, the Board of Grievances has jurisdiction over disputes with the government and over commercial disputes.

In October 2007, King Abdullah issued a royal decree to overhaul the Kingdom's judicial system, including allocating SAR 7 billion (approximately \$1.9 billion) to train judges and build new courts. The decree establishes two Supreme Courts, a general court, an administrative court and specialized labor and commercial tribunals, but implementation has been slow.

Business Visas

All visitors to Saudi Arabia must have a Saudi sponsor in order to obtain a business visa to enter Saudi Arabia. Business visitors and foreign investors can apply through the Saudi Arabian General Investment Authority (SAGIA) for a visitor visa at the Saudi Embassy or Consulates in the United States. Saudi Arabia has also begun to implement a decree stating that sponsorship for certain business visas is no longer required. Based on new instructions, the issuance of a visitor's visa should be affected within 24 hours from the application date.

While most business visas are valid for only one entry for a period of up to three months, the Saudi Embassy in Washington has begun issuing a five year multiple entry visa for selected business people, taking into consideration the principle of reciprocity. Finally, the Saudi Ministry of Foreign Affairs is currently examining the issuance of a visitor's visa at ports of entry for selected nationalities.

Delayed Payments

Payment delays are on the rise in the wake of lower oil prices, according to some members of the business community. Some companies carry Saudi government receivables for years before being paid. The government appears committed to clearing remaining arrears, but the problem persists. U.S. companies should check with the U.S. Embassy or Consulates if a problem arises.

Intellectual Property Protection

Saudi Arabia recently undertook a comprehensive revision of its laws covering intellectual property rights to bring them in line with the WTO agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs). The Saudi legal system protects and facilitates acquisition and disposition of all property rights, including intellectual property. The Saudi government recently updated the Trademark Law (2002), the Copyright Law (2003) and the Patent Law (2004), with the dual goals of TRIPs compliance and effective deterrence against violators. In 2008, the Violations Review Committee created a website and has populated it with information on current cases. The government also endorsed the country's joining of the "Paris Convention for Protection of Industrial Property" and the "Berne Convention for the

Protection of Literary and Artistic Works." Although intellectual property protection has steadily increased in the Kingdom, intellectual piracy remains a problem.

Arab League Boycott

The Gulf Cooperation Council (Saudi Arabia, Kuwait, Bahrain, Oman, Qatar and the United Arab Emirates) announced in the fall of 1994 that its members would no longer enforce the secondary and tertiary aspects of the Arab League Boycott. The primary boycott against Israeli companies and products still applies. Advice on boycott and anti-boycott related matters are available from the U.S. Embassy or from the Office of Anti-Boycott Compliance in Washington, D.C.

Government Procurement

Government contracts on project implementation and procurement strongly favor Saudi and GCC nationals. Most Saudi defense contracts, however, are negotiated outside these regulations on a case-by-case basis. Saudi Arabia published its revised government procurement procedures in August 2006. Foreign suppliers participating in government procurement are required to establish a training program for Saudi nationals. The Saudi Arabian government has yet to initiate accession procedures to join the WTO Government Procurement Agreement as agreed during the Kingdom's accession process. In addition, Saudi Arabia gives priority in government purchasing to GCC products. These items receive up to a 10 percent price preference over non-GCC products in all government procurements in which foreign suppliers participate.

Shipping

Saudi Arabia gives preference to national carriers for up to 40 percent of government-related cargos. Two local companies take full advantage of this situation. Standards and Labeling

As part of the GCC Customs Union, the six Member States are working toward unifying their standards and conformity assessment systems. Each Member State currently continues to apply its own standard or a GCC standard in this sector. A new ICCP mandates that a Certificate of Conformity must accompany all consumer goods exported to Saudi

Arabia. Labeling and marking requirements are compulsory for any products exported to Saudi Arabia.

Trade Events

C3 Saudi International Healthcare Forum

April • Riyadh, Saudi Arabia Healthcare themes and issues. Drawing on high level officials and executives from both the public and private sectors in the U.S. and Saudi Arabia.

Saudi Health Exhibition and Conference

May • Riyadh, Saudi Arabia Showcasing the latest products, technology and services. This is the only event with the full support of the Ministry of Health and will cover the full spectrum of healthcare.

Resources

Saudi Ministry of Health, moh.gov.sa/en

Executive Board of the Saudi Health Ministers

Council, sgh.org.sa/en-us/home.aspx